K012948
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Summary of Safety and Effectiveness

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

General Information

Submitter: Boston Scientific
480 Pleasant Street
Watertown, MA 02172
617-923-1720

Contact Person: Nicholas Condakes

General Provisions

Trade Name: Vaxcel™ Dialysis Cathcter

Classification Name: Catheter, Hemodialysis

Name of Predicate Devices

Vaxcel™ Dialysis Catheter

Classification

Class III

Performance Standards

Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act

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Intended Use and Device Description

The Vaxcel™ Dialysis Catheter is designed for chronic hemodialysis and apheresis. The major components of the Vaxcel™ Dialysis Catheter are the dual lumen catheter, hub, injection cap, introducer sheath/dilator and metal tunneler with protective sheath.

Summary of Substantial Equivalence

The Vaxcel Dialysis catheters have been tested and compared to the predicate device. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2001

Mr. Nicholas Condakes
Regulatory Affairs Specialist
Boston Scientific Corporation
Medi-Tech®
One Boston Scientific Place
NATICK MA 01760-1537

Re: K012948
Trade/Device Name: Vaxcel™ Dialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: August 31, 2001
Received: September 4, 2001

Dear Mr. Condakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known) K012948

Device Name: Vaxcel™ Dialysis Catheter

Indications for Use The Vaxcel™ Dialysis Catheter is designed for chronic hemodialysis and apheresis.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The Counter Use _____ (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012948